

Message

---

**From:** Stepp, Cathy [stepp.cathy@epa.gov]  
**Sent:** 3/16/2019 3:32:21 PM  
**To:** Newton, Cheryl [Newton.Cheryl@epa.gov]  
**CC:** Thiede, Kurt [thiede.kurt@epa.gov]; Nam, Ed [nam.ed@epa.gov]; Nelson, Leverett [nelson.leverett@epa.gov]  
**Subject:** Re: Thank you for FDA/EPA call regarding EtO sterilization

Excellent! Thank you!

Sent from my iPhone

On Mar 15, 2019, at 5:37 PM, Newton, Cheryl <[Newton.Cheryl@epa.gov](mailto:Newton.Cheryl@epa.gov)> wrote:

Hi Cathy, Kurt - Sharing some information from today's call with FDA. Bill W was the senior EPA participant. I will share more information from this call next week; it was a really helpful and needed exchange. Thanks

Sent from my iPhone

Begin forwarded message:

**From:** "Woods, Clint" <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)>  
**Date:** March 15, 2019 at 3:58:20 PM CDT  
**To:** "Schwartz, Suzanne" <[Suzanne.Schwartz@fda.hhs.gov](mailto:Suzanne.Schwartz@fda.hhs.gov)>  
**Cc:** "Richardson, RobinH" <[Richardson.RobinH@epa.gov](mailto:Richardson.RobinH@epa.gov)>, "Siegel, Kathryn" <[siegel.kathryn@epa.gov](mailto:siegel.kathryn@epa.gov)>, "Paulos, Lauren" <[Lauren.Paulos@fda.hhs.gov](mailto:Lauren.Paulos@fda.hhs.gov)>, "Nam, Ed" <[nam.ed@epa.gov](mailto:nam.ed@epa.gov)>, "DAmico, Reid \*" <[Reid.DAmico@fda.hhs.gov](mailto:Reid.DAmico@fda.hhs.gov)>, "Rodrick, Christian" <[rodrick.christian@epa.gov](mailto:rodrick.christian@epa.gov)>, "Helms Williams, Emily" <[Emily.HelmsWilliams@fda.hhs.gov](mailto:Emily.HelmsWilliams@fda.hhs.gov)>, "Aguilar, Paul" <[Paul.Aguilar@fda.hhs.gov](mailto:Paul.Aguilar@fda.hhs.gov)>, "Claverie, Elizabeth F" <[Elizabeth.Claverie@fda.hhs.gov](mailto:Elizabeth.Claverie@fda.hhs.gov)>, "Tomasello, Jennifer" <[Jennifer.Tomasello@fda.hhs.gov](mailto:Jennifer.Tomasello@fda.hhs.gov)>, "Marders, Julia A" <[Julia.Marders@fda.hhs.gov](mailto:Julia.Marders@fda.hhs.gov)>, "Ross, Aftin" <[Aftin.Ross@fda.hhs.gov](mailto:Aftin.Ross@fda.hhs.gov)>, "Koerber, Mike" <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>, "Newton, Cheryl" <[Newton.Cheryl@epa.gov](mailto:Newton.Cheryl@epa.gov)>  
**Subject:** Re: Thank you for FDA/EPA call regarding EtO sterilization

Suzanne,

Thanks so much for the time today and your thorough follow up. I have copied Mike Koerber ([Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)), our POC, as well as Cheryl Newton from Region 5. We look forward to working with you.

Clint Woods

Deputy Assistant Administrator

Office of Air and Radiation, U.S. EPA

202.564.6562

On Mar 15, 2019, at 4:45 PM, Schwartz, Suzanne <[Suzanne.Schwartz@fda.hhs.gov](mailto:Suzanne.Schwartz@fda.hhs.gov)> wrote:

A quick note of appreciation to our US EPA colleagues for this morning's highly informative discussion on EtO sterilization.

I did not capture all of the names of the call participants and wanted to make sure that you relay our thanks to them on FDA's behalf.

In addition, there were two specific due outs for which we were responsible to get back to you and I wanted to do so promptly.

- (1) FDA POCs for continued dialogue on this matter should be Liz Claverie [Elizabeth.Claverie@fda.hhs.gov](mailto:Elizabeth.Claverie@fda.hhs.gov) and myself [Suzanne.Schwartz@fda.hhs.gov](mailto:Suzanne.Schwartz@fda.hhs.gov)
- (2) After conferring internally, FDA would like to join US EPA in its interactions with Sterigenics regarding the facility under seal order. One caveat – if this discussion also includes State of Illinois EPA Attorney General's Office, there are specific procedural measures that have to be taken first by the State AG office before FDA would be able to participate on this call.

Lastly and very importantly, we would like to engage collaboratively regarding EPA's imminent proposed rulemaking that would impact these facilities.

US EPA mentioned that its POC for us is Mike Herber(?). I am not sure I captured Mike's last name correctly and I do not have his email address. Can a colleague from US EPA headquarters in DC forward this email to him and provide us with his contact information?

Best,

Suzanne

Suzanne B. Schwartz, MD, MBA  
Associate Director for Science & Strategic Partnerships  
Office of the Center Director  
Center for Devices & Radiological Health  
Us Food & Drug Administration  
10903 New Hampshire Ave Bldg 66, Room 5434  
Silver Spring, Maryland 20993  
Work: 301-796-6937  
Cell: Personal Privacy / Ex. 6

-----Original Appointment-----

**From:** Williams, Letise **On Behalf Of** Schwartz, Suzanne

**Sent:** Tuesday, March 12, 2019 2:41 PM

**To:** Schwartz, Suzanne; Marders, Julia A; Tomasello, Jennifer; Claverie, Elizabeth F; Aguilar, Paul; Gross, Karas; Helms Williams, Emily;  
[woods.clint@epa.gov](mailto:woods.clint@epa.gov); [richardson.robinh@epa.gov](mailto:richardson.robinh@epa.gov);  
[siegel.kathryn@epa.gov](mailto:siegel.kathryn@epa.gov); Rakosnik, Delaney

**Cc:** Silvis, Lauren; Lauren Paulos ([Lauren.Paulos@fda.hhs.gov](mailto:Lauren.Paulos@fda.hhs.gov)); Nam, Ed; DAmico, Reid \*; Rodrick, Christian

**Subject:** Confirmed: FDA/EPA call regarding EtO sterilization

**When:** Friday, March 15, 2019 11:00 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).

Where: Conference Code / Ex. 6 Dial-In: Conference Phone / Ex. 6 Attendee ID: Conference Code / Ex. 6; Host  
ID (Suzanne): Conference Code / Ex. 6  
Importance: High

**From:** Schwartz, Suzanne <[Suzanne.Schwartz@fda.hhs.gov](mailto:Suzanne.Schwartz@fda.hhs.gov)>  
**Sent:** Monday, March 11, 2019 2:06 PM  
**To:** Siegel, Kathryn <[siegel.kathryn@epa.gov](mailto:siegel.kathryn@epa.gov)>; Claverie, Elizabeth F  
<[Elizabeth.Claverie@fda.hhs.gov](mailto:Elizabeth.Claverie@fda.hhs.gov)>; Richardson, RobinH  
<[Richardson.RobinH@epa.gov](mailto:Richardson.RobinH@epa.gov)>; Woods, Clint <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)>  
**Cc:** Williams, Letise <[Letise.Williams@fda.hhs.gov](mailto:Letise.Williams@fda.hhs.gov)>  
**Subject:** RE: FDA requests a brief meeting

Katie,  
Thank you for your voicemail and email below.

We will postpone this Wednesday's FDA:EPA call regarding EtO sterilization in order to accommodate the availability of both Robin Richardson and Clint Woods, as you have advised.  
By copy on this email, I am asking my executive assistant Letise Williams, to facilitate scheduling a phone discussion with Robin, Clint, you and FDA.

We would be looking at Friday at the earliest. But perhaps next week would be more flexible.

Please reply to all on this email.

Thank you,

Suzanne

Suzanne B. Schwartz, MD, MBA  
Associate Director for Science & Strategic Partnerships  
Office of the Center Director  
Center for Devices & Radiological Health  
Us Food & Drug Administration  
10903 New Hampshire Ave Bldg 66, Room 5434  
Silver Spring, Maryland 20993  
Work: 301-796-6937  
Cell: Personal Privacy / Ex. 6